

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

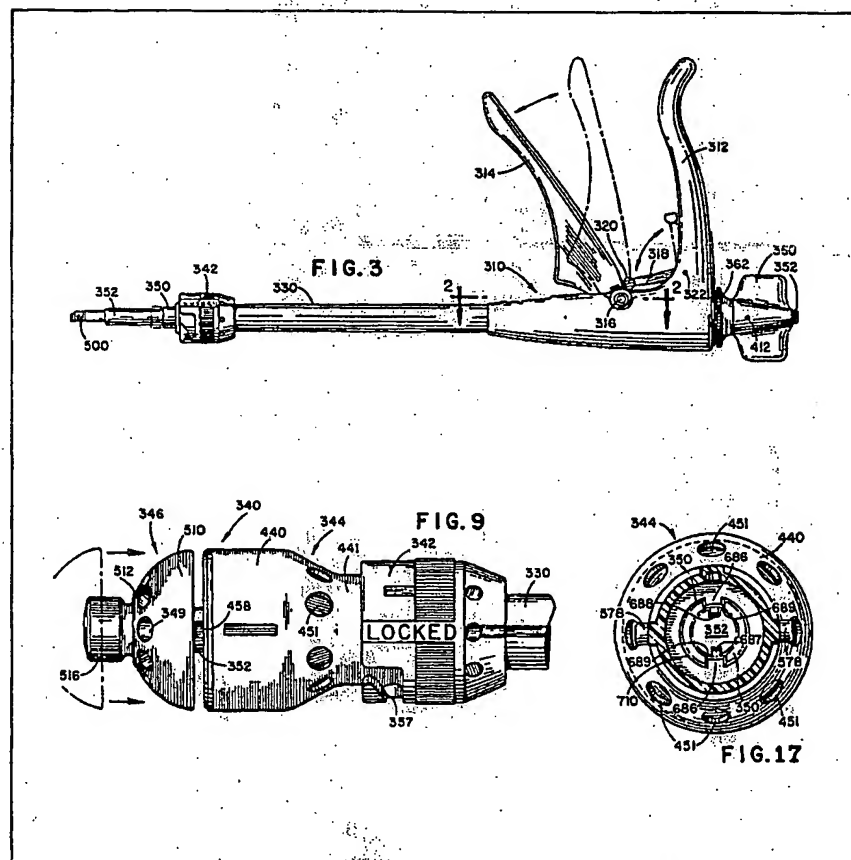
(12) UK Patent Application (19) GB (11) 2 038 692 A

- (21) Application No 7942264
 (22) Date of filing 7 Dec 1979
 (30) Priority data
 (31) 967422
 (32) 7 Dec 1978
 (33) United States of America (US)
 (43) Application published 30 Jul 1980
 (51) INT. CL.³
 A61B 17/11
 B25C 5/02
 (52) Domestic classification
 B4C 104 A3A
 (56) Documents cited
 GB 2016991A
 GB 1241577
 GB 1185292
 GB 1121673
 GB 942122
 (58) Field of search
 B4C
 (71) Applicants
 United States Surgical Corporation,
 150 Glover Street,
 Norwalk,
 Connecticut,
 United States of America.
 (72) Inventors
 Douglas George Nollis
 (74) Agents
 Marks & Clerk

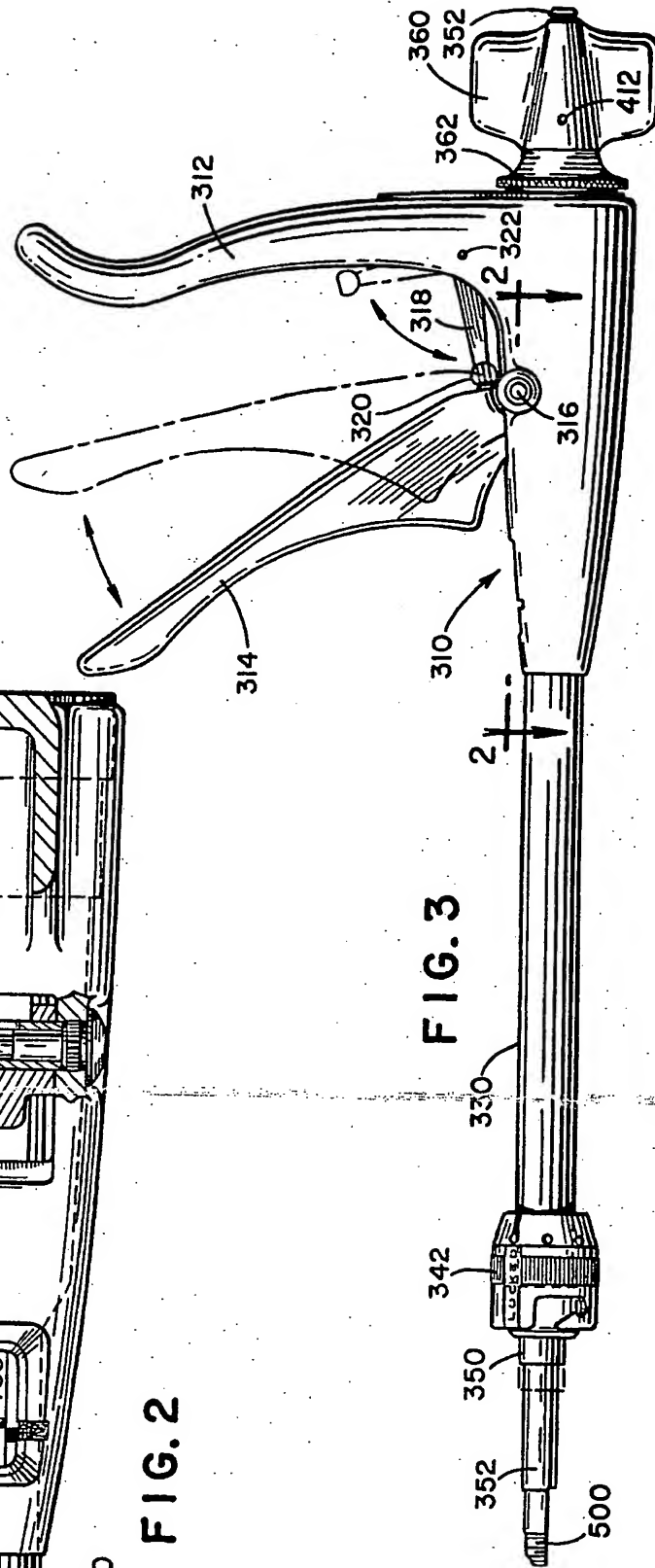
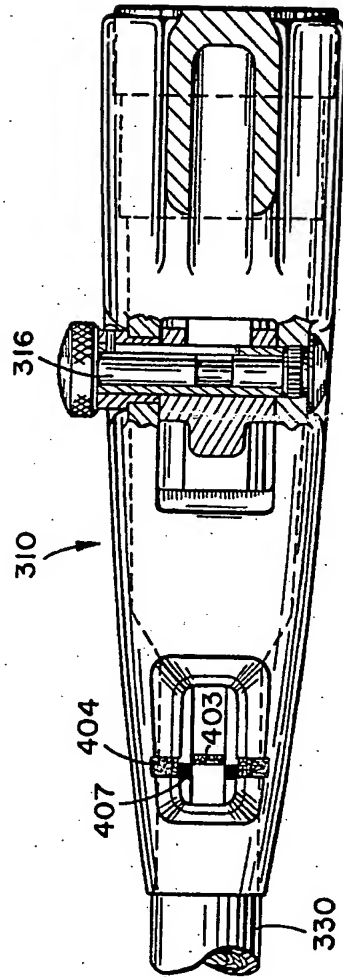
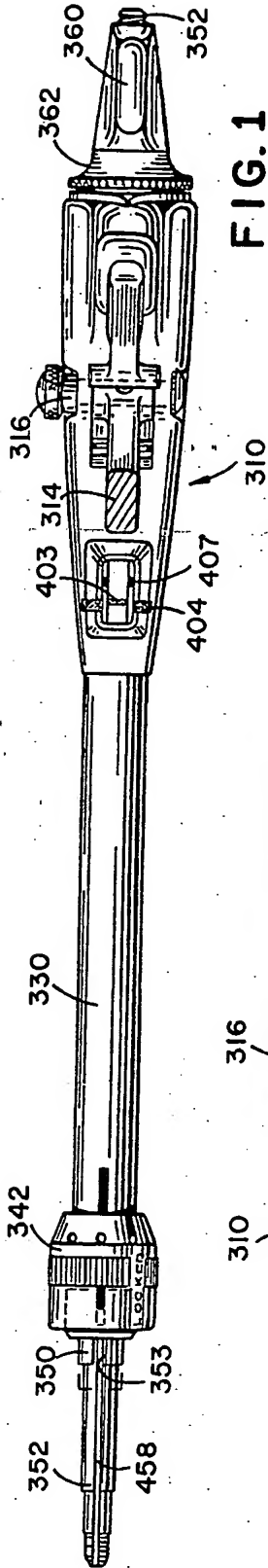
(54) Precisely aligned anastomosis stapling cartridge and instrument

(57) A surgical stapling apparatus comprising a permanent instrument and a disposable cartridge for anastomosing disconnected sections of hollow body organs. The instrument contains a body 330 defining a bore. A tubular member 350, received within the bore, is arranged for reciprocation motion. A first mechanism 314 is provided to reciprocate the tubular member 350 and thus drive the staples. Mounted concentrically within the tubular member is a rod 352, which includes first and second longitudinally extend-

ing keyways (458, 459; figures 1, 10, 20,) of different dimensions. A second mechanism 360 is provided to reciprocate the rod 352. The disposable cartridge 340 comprises a rigid staple-carrying part 344 and a rigid anvil-carrying part 346. The staple-carrying part and the anvil-carrying part each include first and second keys 687, 688 configured to mate, respectively, with the first and second keyways 458, 459 to directly mount the parts in a predetermined indexed orientation on the rod. Movement of rod 352 by screw 360 adjusts the separation of anvil corner 346 and staple corner 344 to facilitate gripping of the organs to be stapled.



GB 2 038 692 A



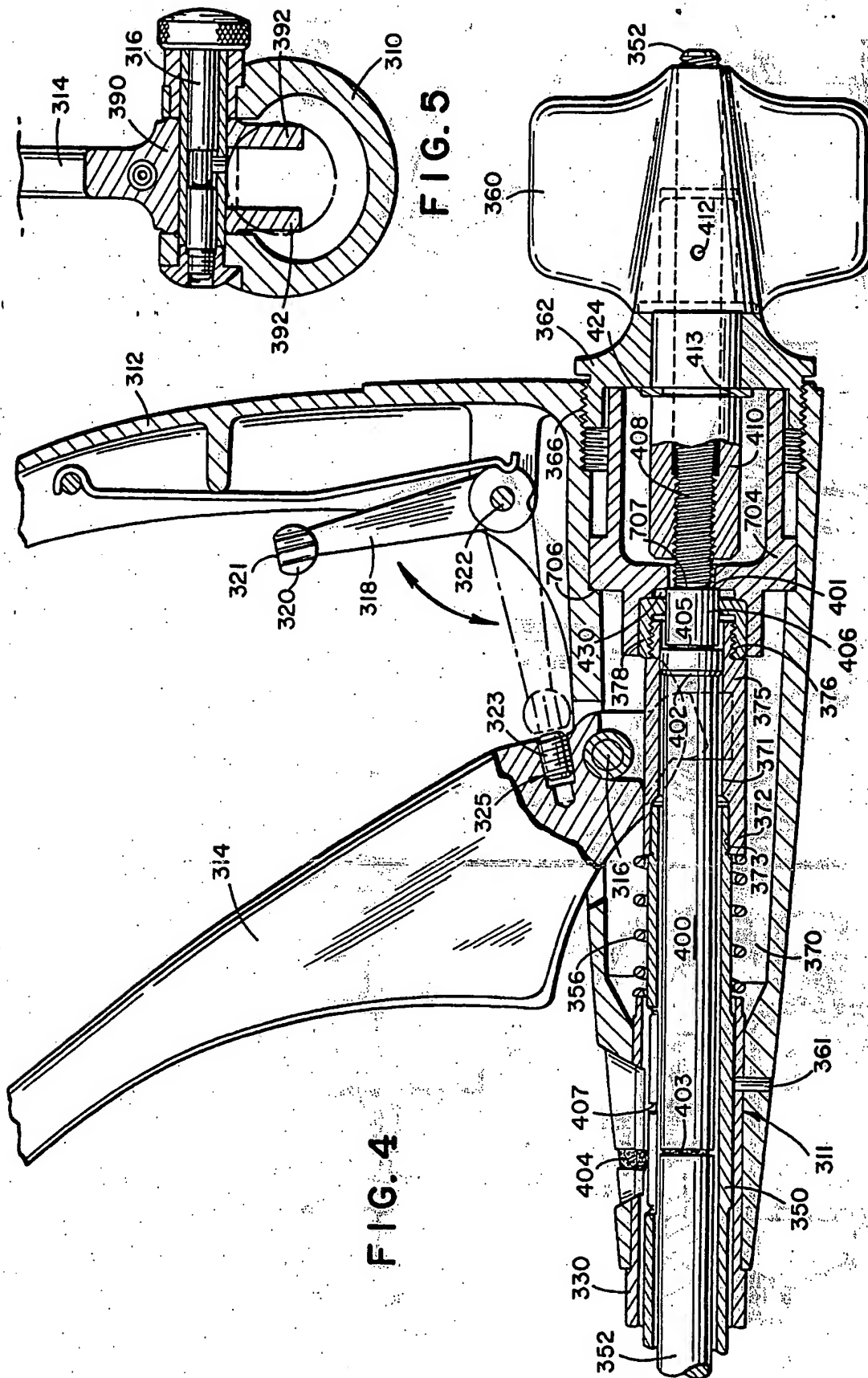


FIG. 6

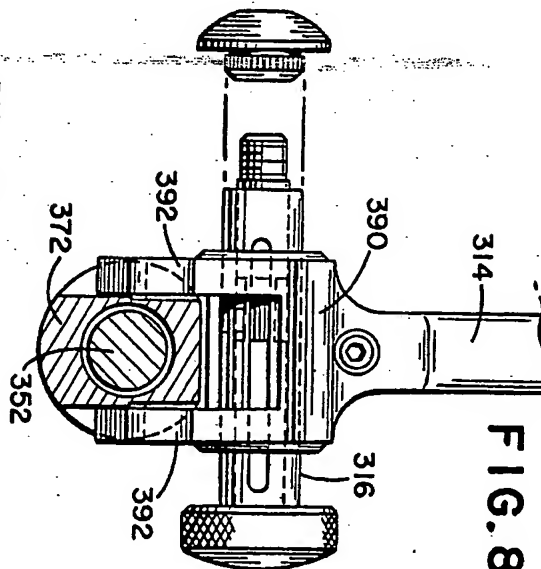
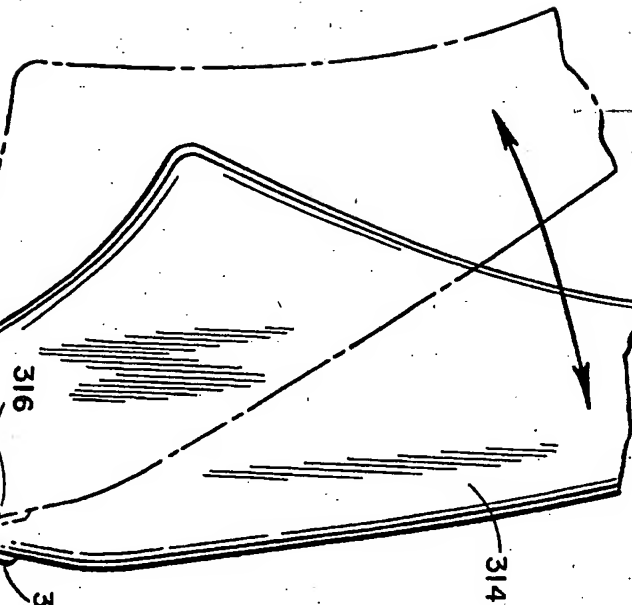
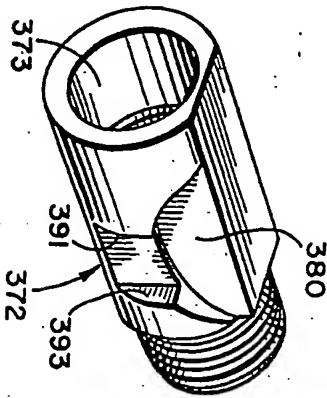
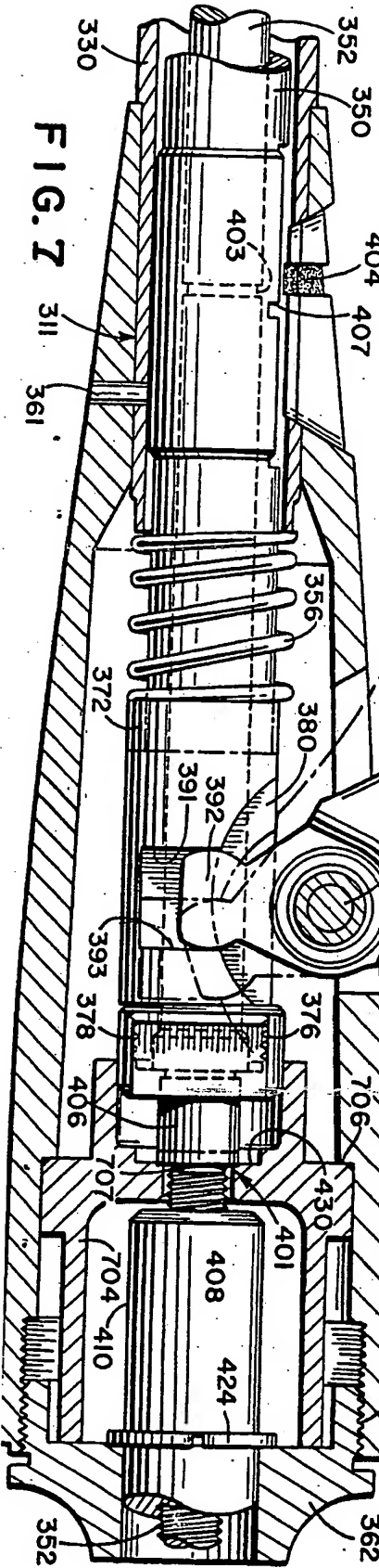
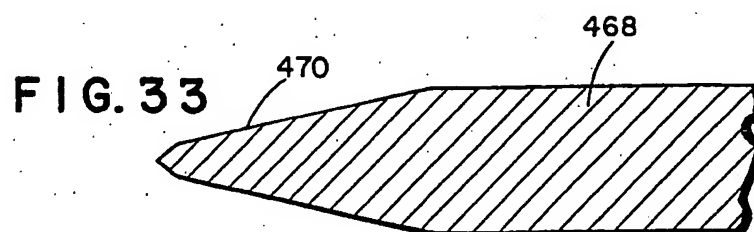
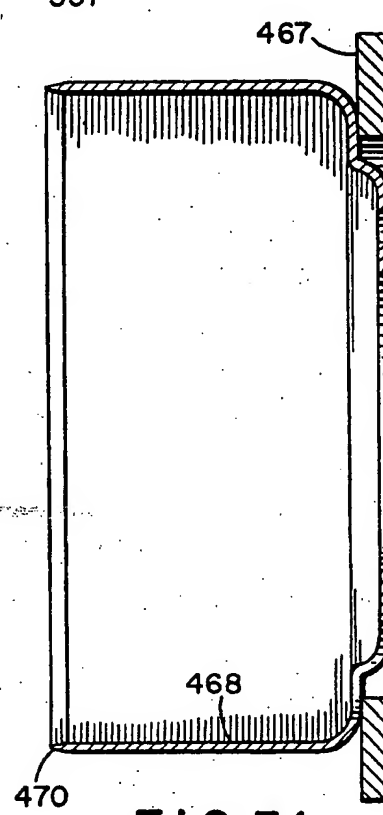
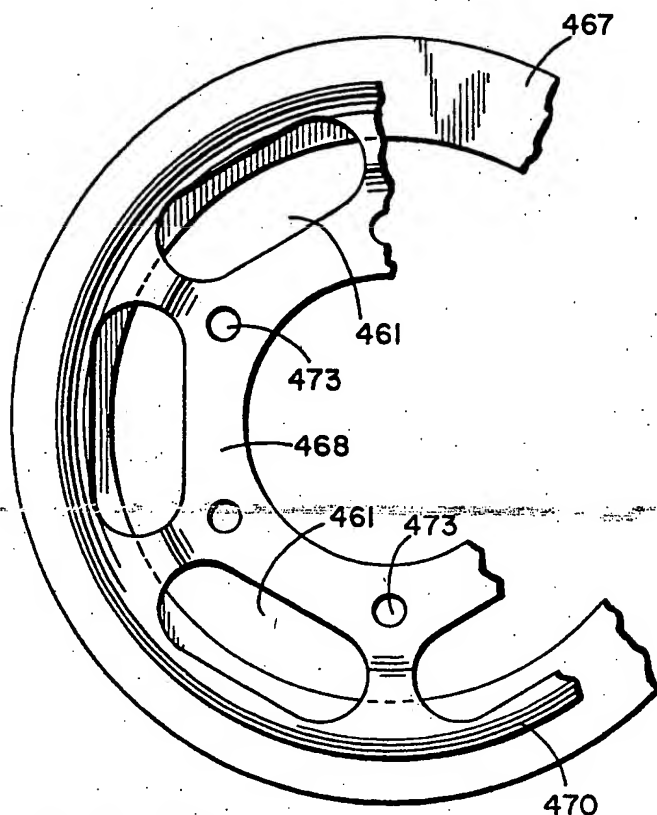
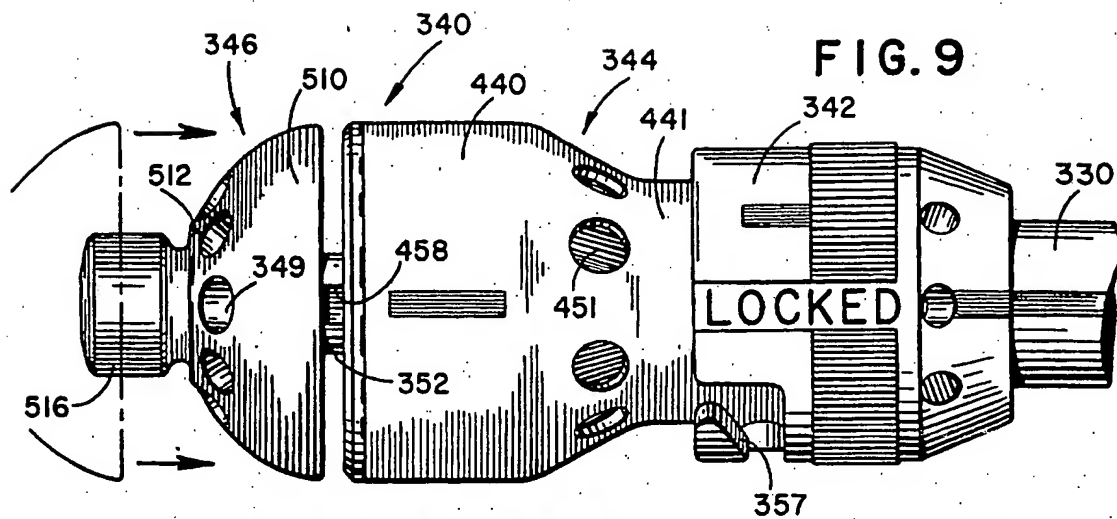


FIG. 8

FIG. 7





2038692

5/11

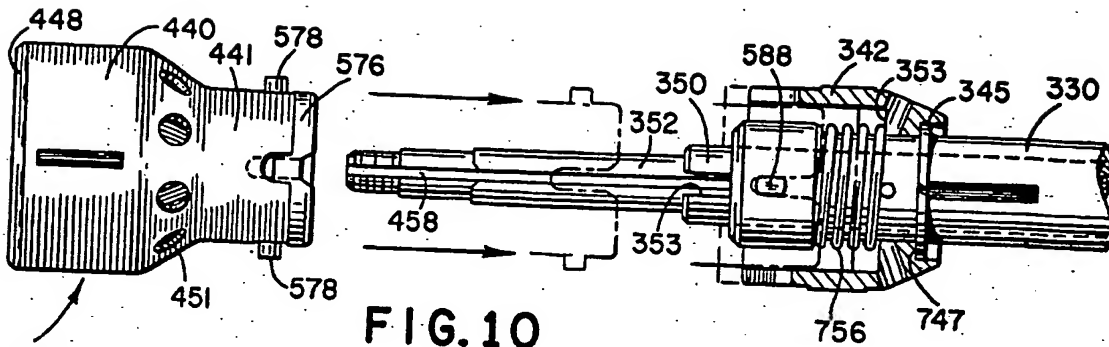


FIG. 10

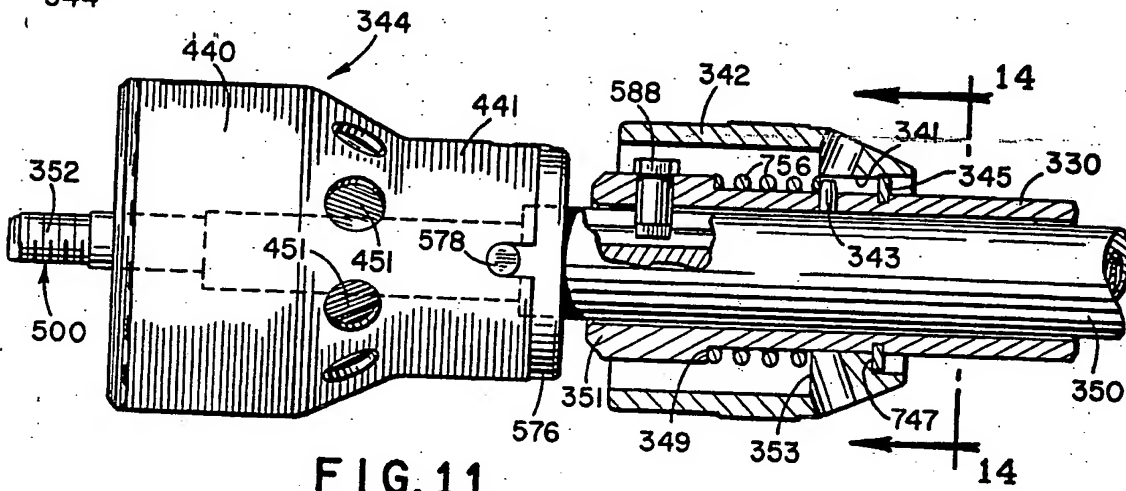


FIG. 11

FIG. 12

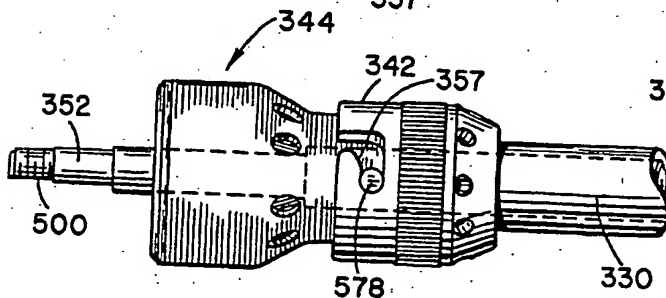
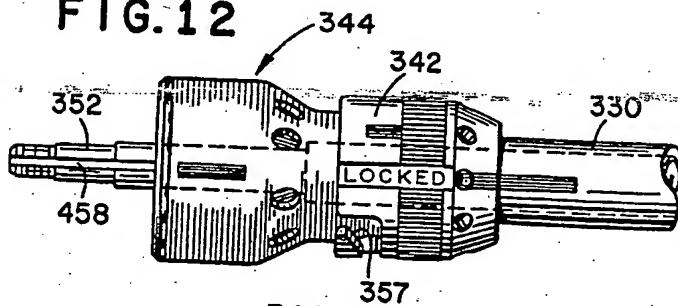


FIG. 13

FIG. 14

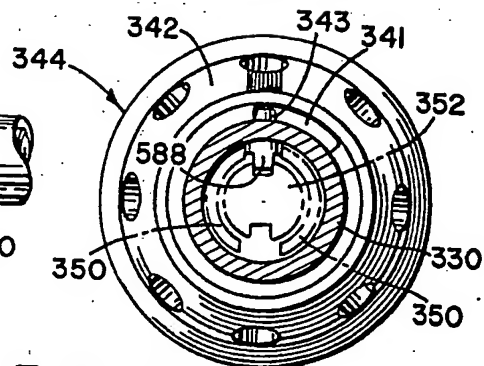
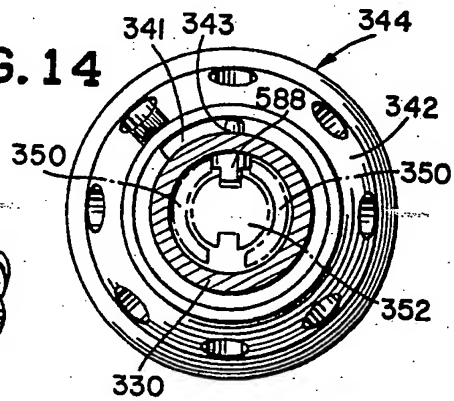
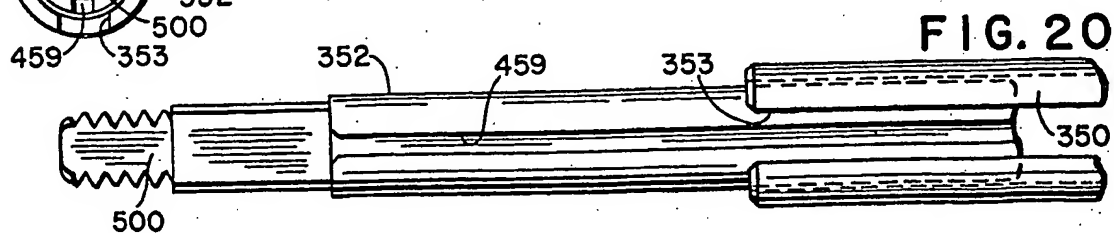
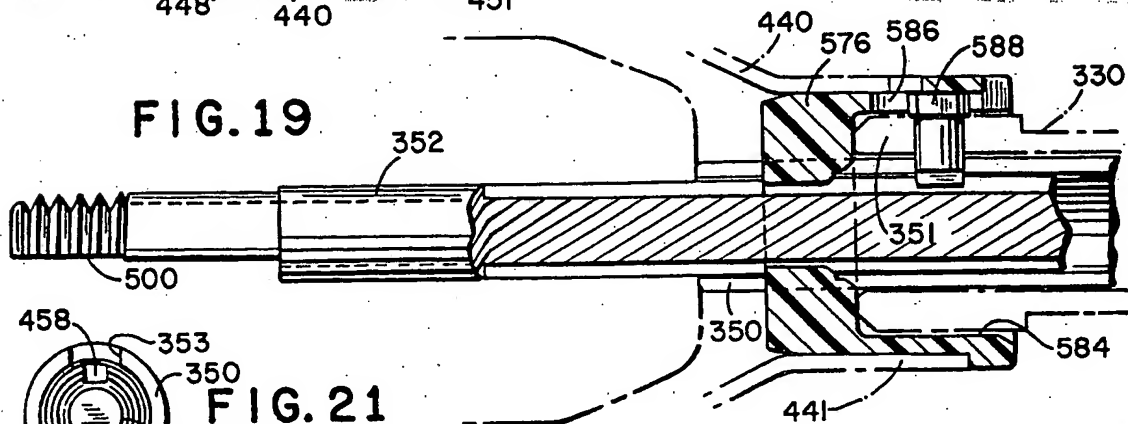
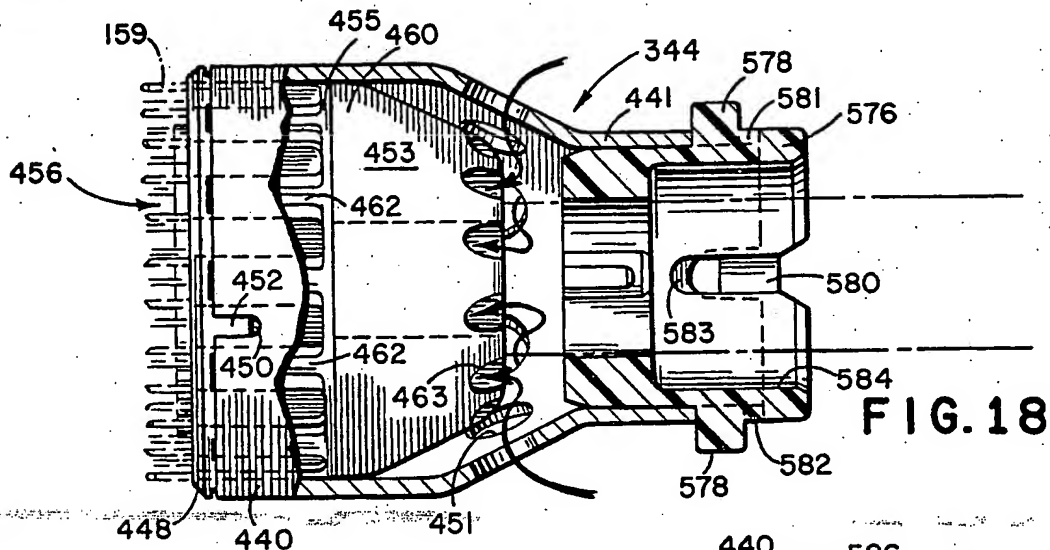
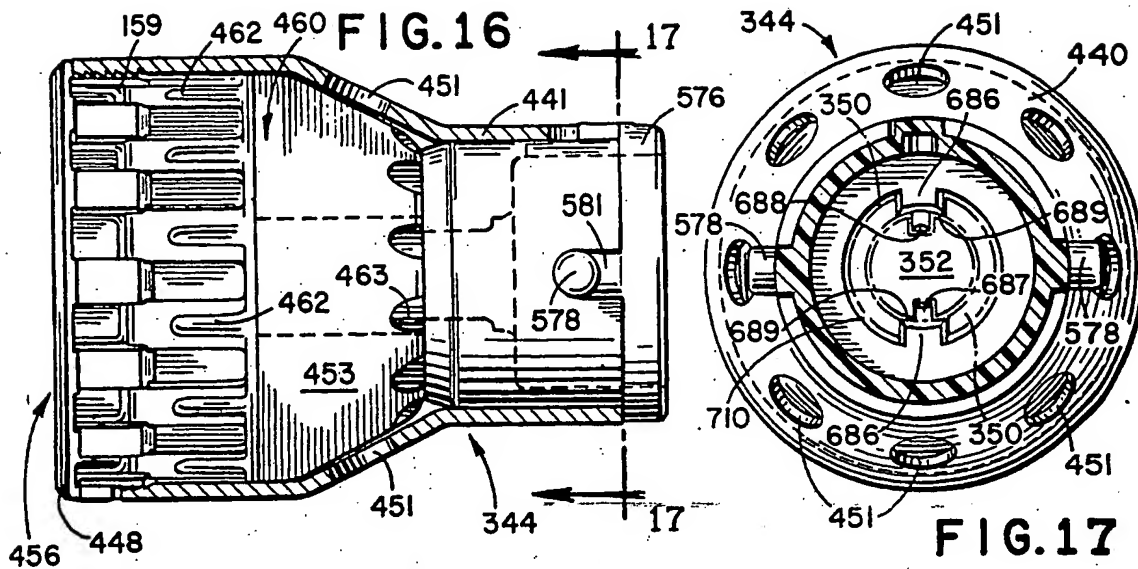


FIG. 15

6/11



7/11

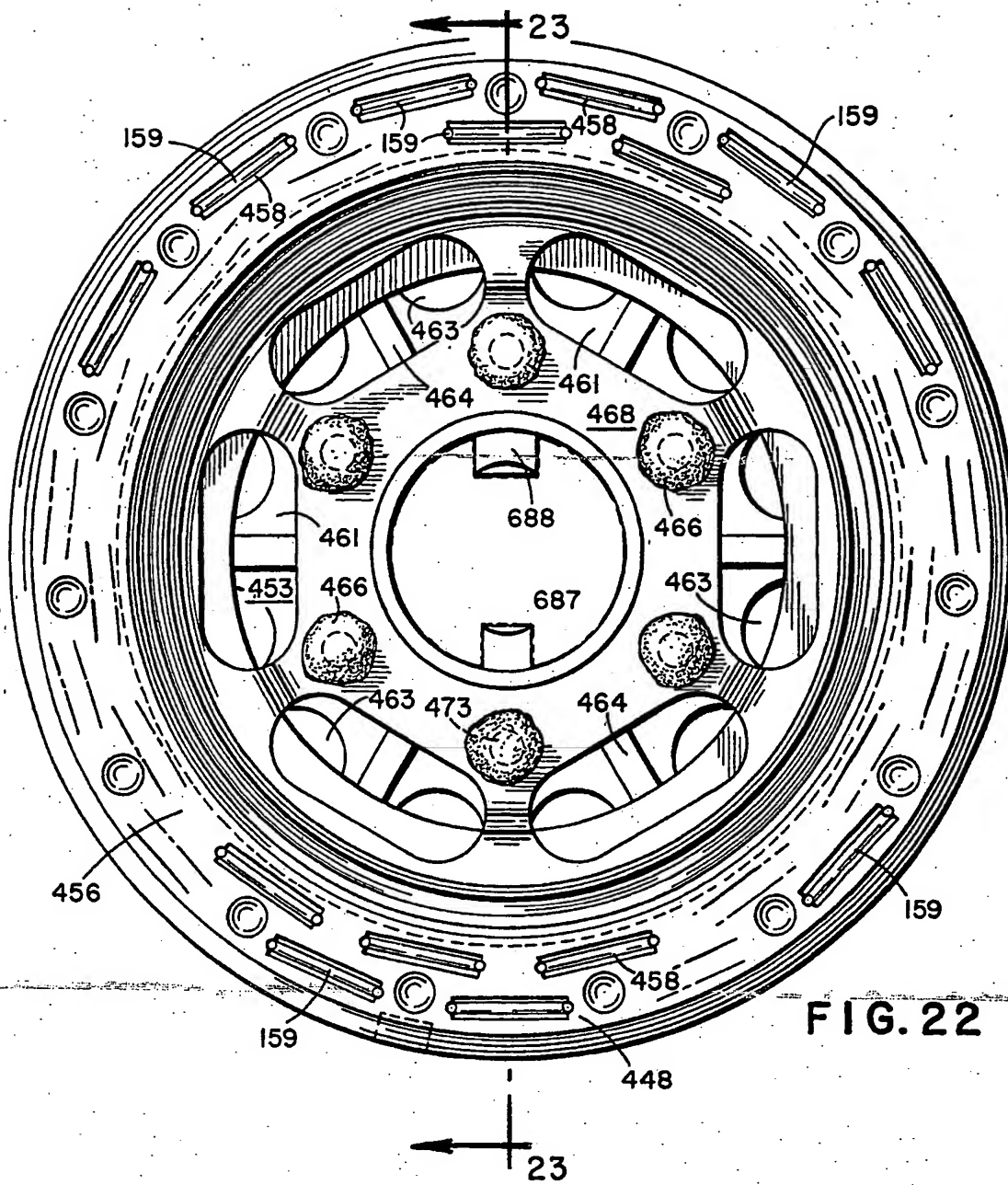


FIG. 22

FIG. 28

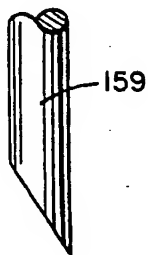


FIG. 29

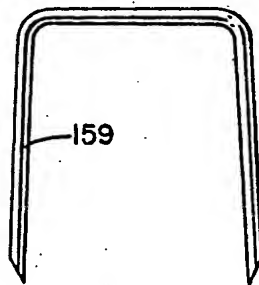
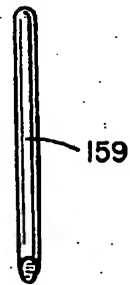
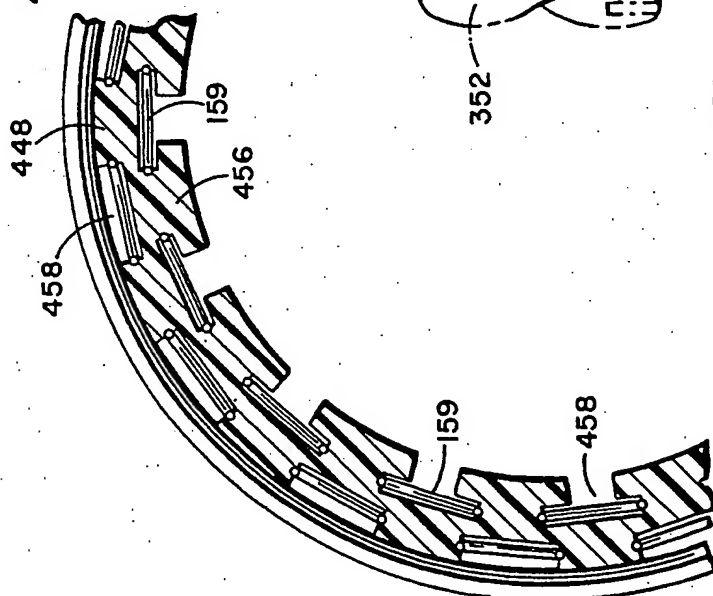
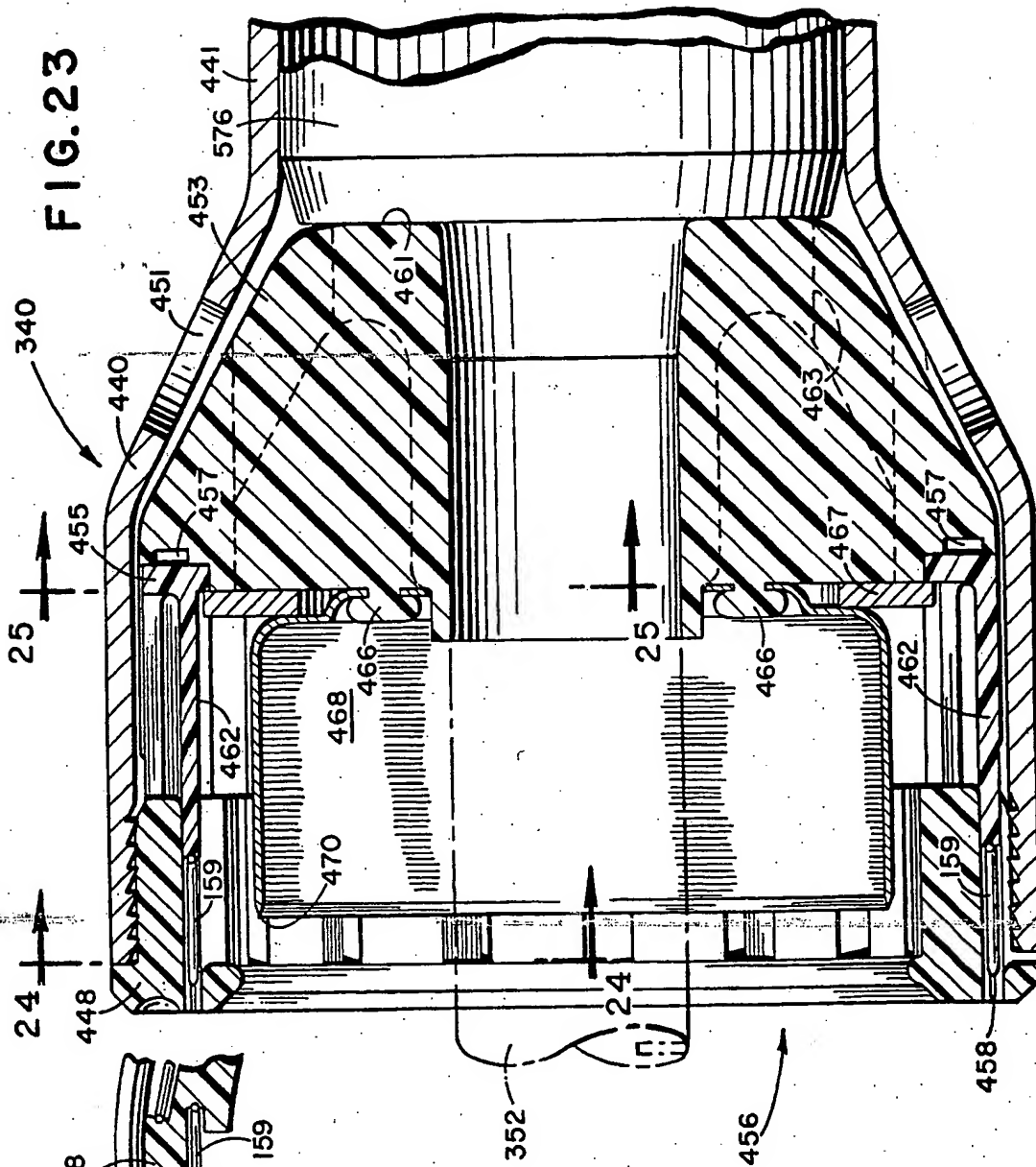


FIG. 30





9/11

FIG. 26

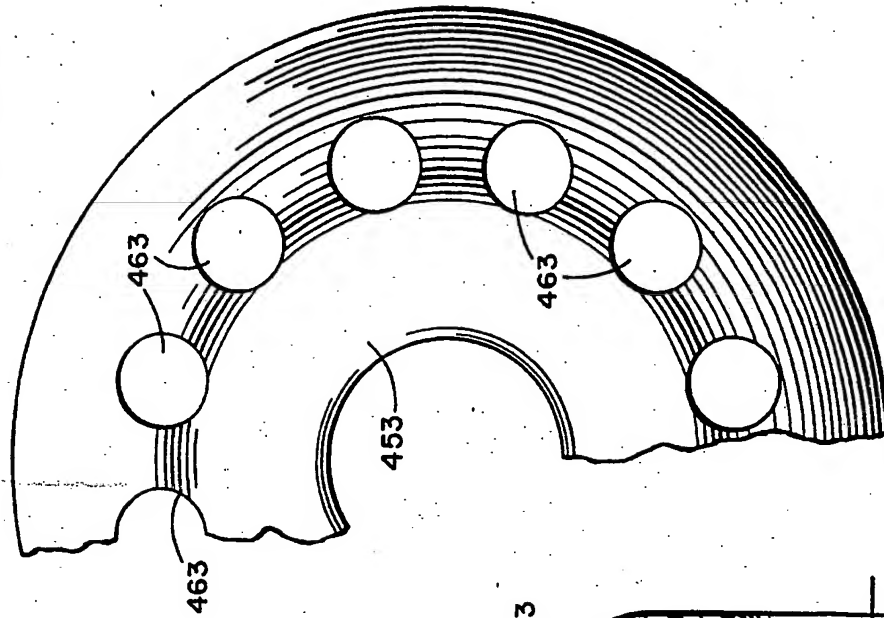


FIG. 25

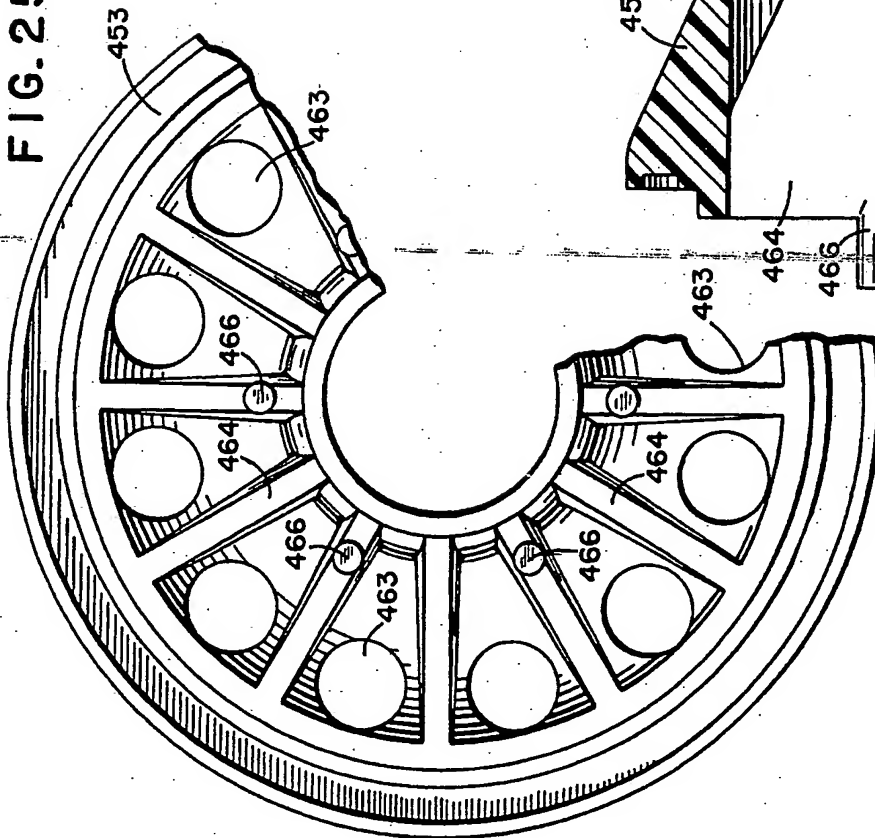
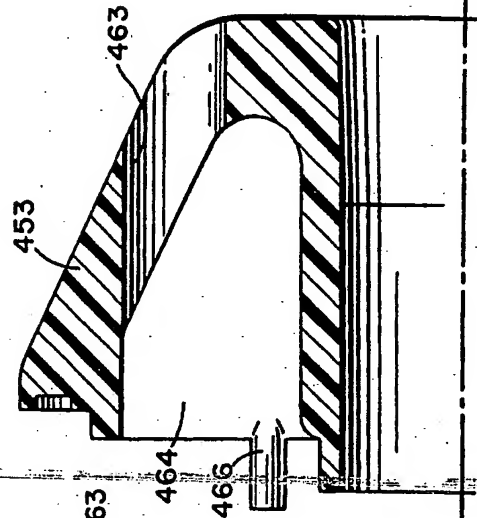


FIG. 27



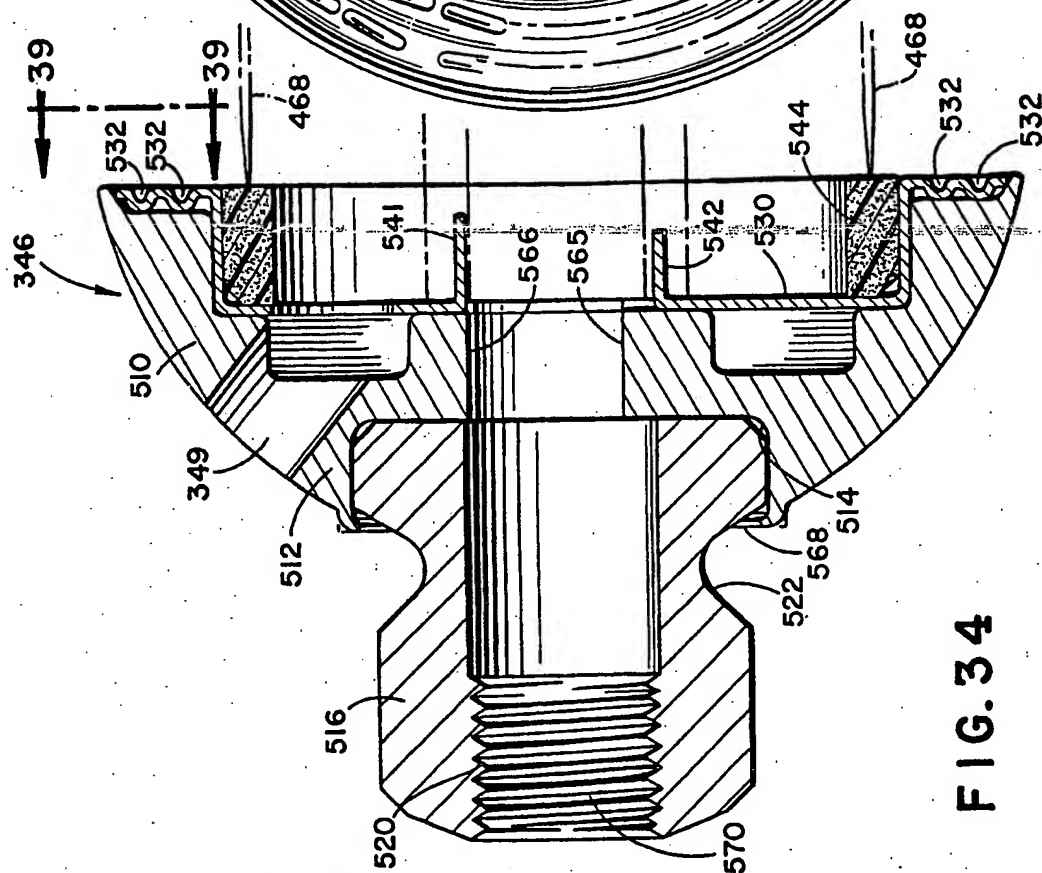
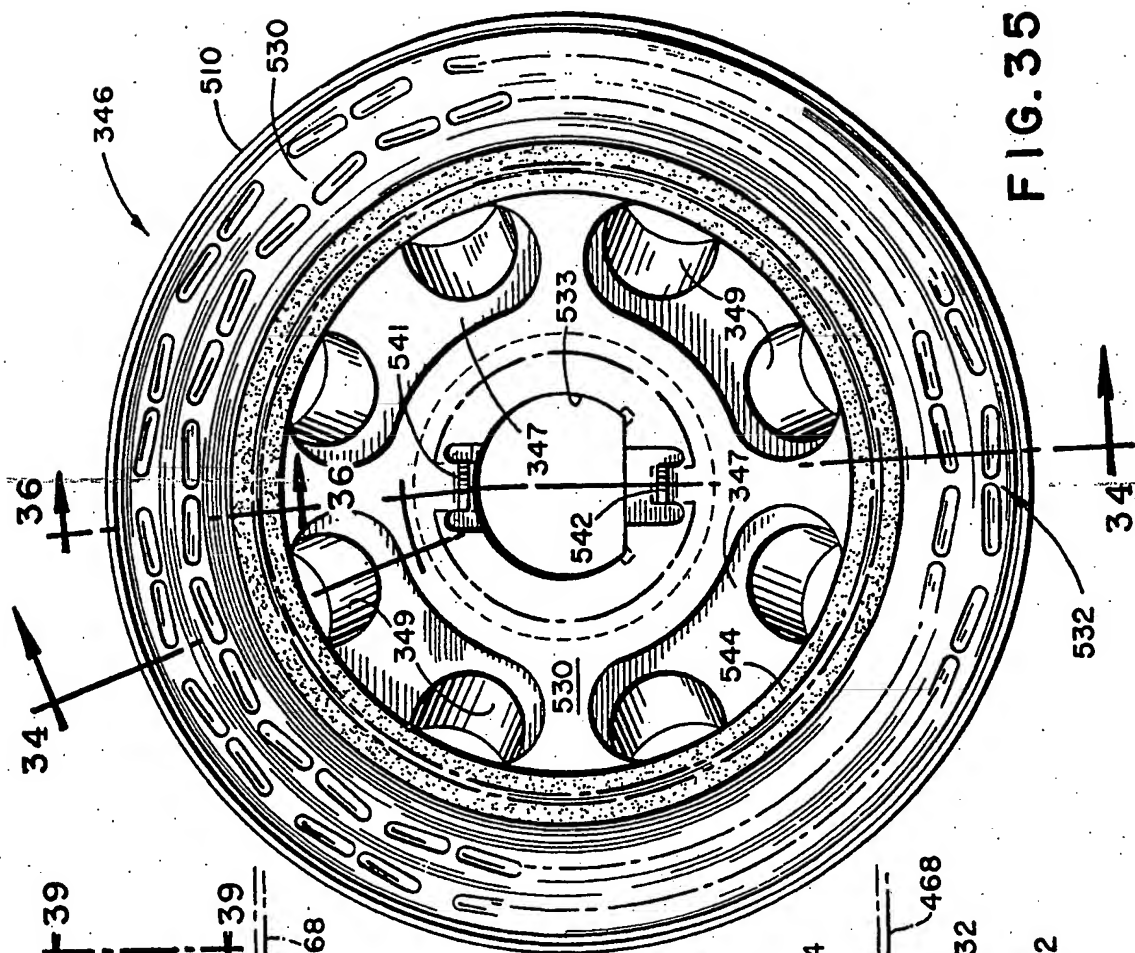


FIG. 37

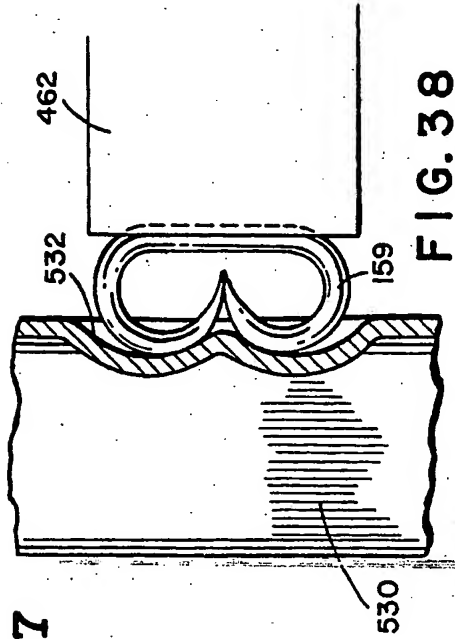
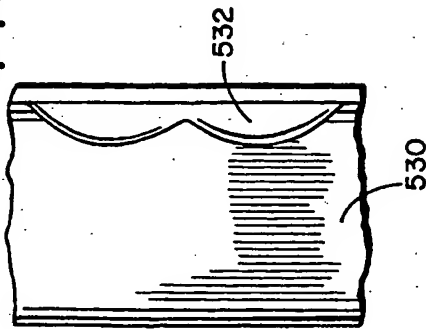


FIG. 39

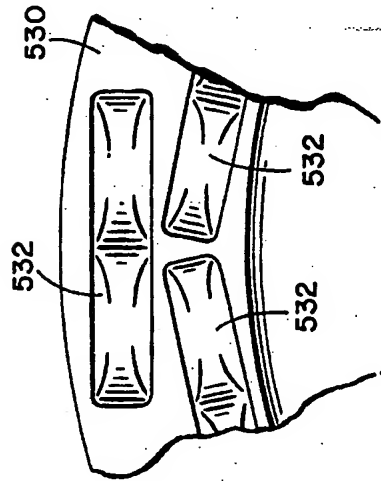


FIG. 36

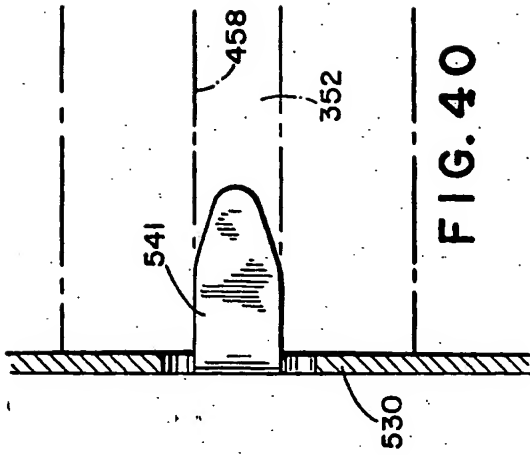
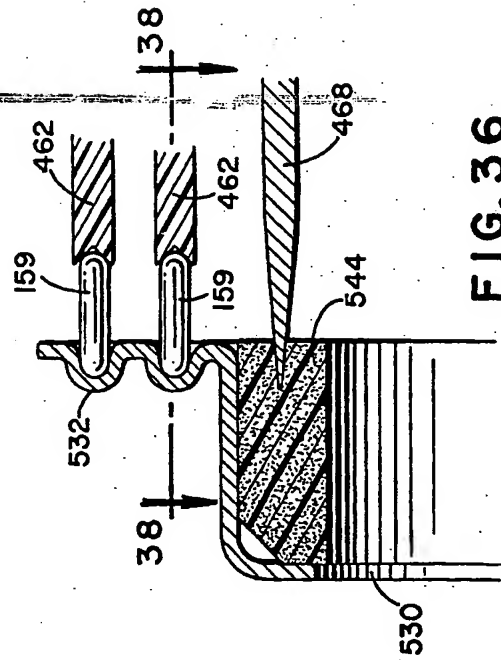
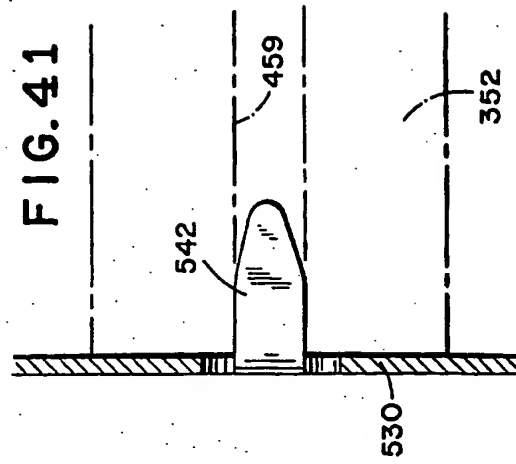


FIG. 41



SPECIFICATION

Precisely aligned anastomosis stapling cartridge and instrument

5

This invention relates to surgical instruments, in general, and to an instrument using a precisely aligned disposable cartridge for surgical stapling of hollow body organs, in particular.

- 10 Presently in the prior art, several instruments are known for circular joining by staples of hollow body organs. United States Patents Nos. 3,638,652, 3,552,626, 3,388,487 and 3,193,165 all relate to instruments of this type, which are useful in surgical
- 15 procedures involving the colon and the esophagus. Despite the fact that these instruments are known in the prior art, they have never been introduced into clinical use in the United States. These instruments, which are disclosed in the aforementioned patents,
- 20 have the important drawback of requiring hand loading of the suturing staples into the staple magazine of the instrument after each use of the instrument. This means that once the instrument is actuated and its staples ejected and clinched, it must
- 25 then be cleaned before the magazine can be manually refilled with staples. While being refilled, the instrument, of course, is inoperative and may not be further used in the on-going surgical operation. The aforementioned U.S. Patent No. 3,552,626 discloses a
- 30 form of the instrument in which the staple magazine and associated anvil of the instrument are interchangeable so that different sizes may be mounted on the same instrument body, but this arrangement is solely for the purpose of accommodating hollow
- 35 body organs of different sizes.

- The present invention is directed to an instrument of the type generally described and was developed to overcome the drawbacks and disadvantages which one experiences when attempting
- 40 to use similar instruments according to prior art teachings and, most notably, those teachings which are contained in the aforementioned patents. One of the principal benefits results from providing the staple carrying cartridge part and the staple clinching anvil part as disposable elements and, thus,
- 45 the staple forming parts, which are subject to wear from usage and/or damage from cleaning and storage, are furnished as new parts for each stapling procedure. The parts most likely to wear or damage
- 50 are the pusher fingers, which eject the staples from the cartridge and the anvil, against which the staple legs are clinched or formed. Additionally, successive uses of an instrument during a surgical procedure are easily attained simply by detaching a spent
- 55 cartridge and replacing with a fresh cartridge. Keying of the parts of the disposable cartridge to each other and to the body of the instrument is also a feature of the invention to insure that all parts are in the correct orientation and properly indexed; hence,
- 60 when the instrument is actuated, the staples are ejected through the tissue of the hollow body organ and clinched to effect the desired staple line.

- The present invention provides an instrument for effecting end-to-end anastomoses, side-to-side
- 65 anastomoses, or end-to-side anastomoses by means

of a pair of concentric circles of staples to ensure a high margin of security in maintaining the desired tissue joining. The present invention, further provides a unique disposable cartridge, and a precise

70 cooperation between the cartridge, the anvil and the instrument for staple forming alignment. Variations in staple dimensions and array patterns are easily provided by a variety of cartridge designs. Unique provision is made for easy removal of the instrument

75 from the stapled anastomosis. Further, the interior of the stapling mechanism is generously vented to prevent the build up of excessive pressure in the tissue confined within the stapling mechanism while the tissue is being compressed and clamped prior to

80 and during the actual firing of the staples and the excision of the excess tissue in the lumen of the anastomosis.

Further advantages and details of the present invention will become more evident from a consideration of the following descriptive text, when taken in conjunction with the appended drawings in which:

Figure 1 is a top plane view cut through the trigger of an embodiment of the surgical stapling instrument with the bayonet in the unlocked position.

- 90 *Figure 2* is an enlarged plan view showing the pivot pin structure in section taken along lines 2-2 of *Figure 3*.

Figure 3 is a side elevation of the instrument of *Figure 1*.

- 95 *Figure 4* is a longitudinal section through the body of the instrument of *Figure 1*.

Figure 5 is a cross section through the pivot pin of *Figure 4*.

Figure 6 is a perspective view of the pusher hub.

- 100 *Figure 7* is a longitudinal section of the instrument of *Figure 4*.

Figure 8 is a cross section through the pivot pin of *Figure 7* with the trigger in elevation.

- 105 *Figure 9* is a side elevation of a second embodiment of the disposable cartridge showing the anvil-carrying and staple-carrying parts.

Figure 10 is a top plan of the staple-carrying part of *Figure 9* and the front of instrument of *Figure 1* with the bayonet sleeve in section.

- 110 *Figure 11* is an enlarged side elevation of the staple-carrying part and front of instrument with the bayonet mounting structure in section.

Figure 12 is a top plan view of the staple-carrying part locked onto the instrument of *Figure 3*.

- 115 *Figure 13* is a side elevation of the structure illustrated in *Figure 12*.

Figure 14 is a sectional view of the bayonet assembly in the unlocked position as viewed along lines 14-14 of *Figure 12*.

- 120 *Figure 15* is the same view as *Figure 14* but with the bayonet assembly in the locked position.

Figure 16 is a side elevation of the staple-carrying part of *Figure 9* with the main body part in section.

- 125 *Figure 17* is a sectional view taken along lines 17-17 of *Figure 16*.

Figure 18 is a bottom plan view of the staple-carrying part of *Figure 9* with a portion of the main body part in section.

- 130 *Figure 19* is a longitudinal section through the front end of the instrument illustrated in *Figure 1*.

Figure 20 is a bottom plan view of a portion of the rod and driver tube for the embodiment illustrated in Figure 1.

Figure 21 is a front end view of the structure illustrated in Figure 20.

Figure 22 is a front elevation of the fully assembled staple-carrying part of Figure 9.

Figure 23 is a sectional view taken along lines 23-23 of Figure 22.

Figure 24 is a partial section taken along lines 24-24 of Figure 23.

Figure 25 is a front elevation as viewed along lines 25-25 of Figure 23.

Figure 26 is a rear elevation of the pusher back illustrated in Figure 25.

Figure 27 is a partial section through one of the vent holes of the pusher back of Figure 25.

Figures 28 through 30 show the details of the staples.

Figure 31 is a longitudinal section of the knife and support ring.

Figure 32 is a partial plan view of the structure illustrated in Figure 31.

Figure 33 is a sectional view of the tip of the knife of Figure 31.

Figure 34 is a longitudinal section of the anvil-carrying assembly of Figure 9.

Figure 35 is an end plan view of the anvil-carrying assembly of Figure 34.

Figure 36 is a sectional view taken along lines 36-36 of Figure 35 with the staples added.

Figure 37 is a plan view of a portion of the anvil of Figure 34.

Figure 38 is a sectional view taken along lines 38-38 of Figure 36.

Figure 39 is a partial front elevation as viewed along lines 39-39 of Figure 34.

Figure 40 is a schematic view to show the detail of the top indexing key of the anvil of Figure 34.

Figure 41 is a schematic view to show the detail of the bottom indexing key of the anvil of Figure 34.

Referring now to Figures 1 through 41, a preferred embodiment of the instrument with disposable cartridge is depicted. As shown in Figures 1 through 8, the instrument comprises a main body or housing 310 defining a throughbore 311 and having an integrally formed rear handle part 312. Projecting from the body 310 is a handle part 314, pivotably mounted to the body 310 by means of pivot pin assembly 316. The handle part 312 is received in the palm of the hand of the operator and the handle part 314 is grasped by the fingers of the same hand. When the fingers are squeezed toward the palm, handle part 314 is pivoted about pin 316 and brought toward handle part 312. A safety bar 318, terminating in a knob 320 is pivotally mounted on a pin 322 set into the body 310, and serves as a safety to prevent the accidental actuation of handle part 314 as shown by the arrow in Figure 3. As best seen in Figure 4, a set screw 323 is received in a threaded bore 325, contained in handle part 314. The set screw is adjusted and secured by a suitable adhesive, so that the safety bar 318 can move into a locked position without binding on its flat face 321.

Projecting from the forward end of the body or

housing 310 is an outer tube 330 which extends forwardly and terminates at a substantial distance from housing 310. Received on the remote end of tube 330, as best seen in Figure 9, is a disposable cartridge referred to generally by the reference numeral 340. Attachment of disposable cartridge 340 to the tube 330 is effected by means of a bayonet-connecting sleeve 342 (Figure 35) in a manner which will be described hereinafter. This disposable cartridge 340 comprises a staple-carrying member 344 and an anvil-carrying member 346.

With reference to Figures 3 through 8, concentrically mounted within the tube 330, is a driver tube 350 and a rod 352. Driver tube 350 reciprocates within tube 330 and serves as a pusher for ejecting staples; the rod 352 reciprocates independent of driver tube 350 and serves to position the anvil-carrying member 346 relative to the staple-carrying member 344. The rod 352 extends entirely through the instrument with one end projecting out of the front of the instrument to receive and carry the anvil-carrying member 346 and the other end projecting out of the back of the instrument for receiving a wing nut 360. The rear end of the rod 352 is threaded and is in threaded engagement with an internally threaded sleeve extension 410 of wing nut 360.

As shown in Figures 4 and 7, an end cap 362 is applied to the rear of the instrument and effects a closure of throughbore 311. Cap 362 secures stepped bushing 704 against shoulder 706 in throughbore 311. The smallest bore through bushing 704 supports reduced part 406 of the rod 352. The cap 362 contains an external thread that coacts, or threadedly engages, with the thread formed in the terminal part of throughbore 311.

Referring now to Figures 36 through 40, the internal arrangement for the body or housing 310 will now be described in detail. As already noted, the cap 362 contains an external thread which threadedly engages with an internal thread suitably formed in the terminal part of the throughbore 311. This threaded engagement is identified generally by the reference numeral 366. Throughbore 311, at its end proximal to the disposable cartridge mounting, receives the outer tube 330 which extends into the throughbore 311 terminating at the entry to an enlarged region 370 of the bore 311. The body 310 and the tube 330 are rigidly interconnected in the bore 311 by holding pin 361, so that there is no relative motion between them. The driver tube 350 extends coaxially within the sleeve 330 and projects therefrom into the enlarged region 370 whereupon it is fixedly mounted at its end within a pusher hub 372. This hub 372, in turn, is connected by means of threads 376 with a pusher-stop cap 378. The driver tube 350, together with the pusher hub 372 and the cap 378, all move as a unit.

With reference to Figures 4 and 6, the pusher hub 372 is of generally cylindrical shape with a stepped throughbore 371. The larger portion 373 of the bore 371 receives and mounts the reduced end of the driver tube 350. The smaller portion 375 of the bore 371 is of sufficient diameter to allow the rod 352 to freely slide therethrough. Cutout portions 380 are provided on diametrically opposed

sides of the hub 372. These cutouts cooperate with the trigger 314 in a manner described hereinafter to serve as the means by which the driver tube 350 is reciprocated within the outer tube 330 of the instrument.

The arrangement for reciprocating the driver tube 350 is illustrated best in Figures 4 through 7. As already noted, the pusher hub 372 carries the cutouts 380 on diametrically opposed sides. The handle part 314 is provided at its lower end with a yoke 390, the legs of which are identified by the reference numeral 392. These legs 392 are received in the cutouts 380, each of which contains a front wall 391 and a back wall 393.

Pivoting of trigger 314 about pin 316 results in a longitudinally-directed force being exerted on the front walls 391 of the hub 372 by yoke portion 390 of the trigger 314. This results in the forward movement of driver tube 350 within outer tube 330. A spring 356 received around tube 350 in region 370 biases hub 372 against the forward movement produced by handle part 314. The left end of spring 356, as viewed in Figure 7, is held against the end of tube 330.

The rod 352 extends completely through the tube 330 and body 310 of the instrument. The rod is provided with a reduced portion 400 bounded at its rear end by bevelled shoulder 402. Provided near the front of the reduced portion 400 is an indicator groove 403. A groove 405 connects the main portion of the rod with a reduced portion 406, which, in turn, is connected to a threaded reduced portion 408 via a groove 707.

The wing nut 360, which appears at the rear of the instrument, is provided with a sleeve extension 410. The nut 360 is secured to the sleeve extension by a pair of pins 412. A retaining ring 424 is received into a groove 413 for the purpose of securing the wing nut 360 and its sleeve extension 410 onto the end cap 362. The sleeve extension 410, as well as nut 360, defines a throughbore through which rod 352 passes. The front portion of the bore within the sleeve extension 410 is threaded to threadably engage with the threads defined on the reduced portion 408 of the rod 352. By the arrangement described, when the cap 362 is threaded into the body 310 with the wing nut 360 held thereon by means of the retaining ring 424, the wing nut 360 will not translate when rotated because of being secured to the end cap 362 in the manner described. Accordingly, sleeve extension 410, acting as a nut on threaded part of rod 408, will cause the rod 352 to reciprocate.

The shoulder 401 of reduced portion 406 acts as a stop working against a shoulder 430 defined in the bushing 704. The furthest position of the rod 352, that it may assume when driven to the right by means of sleeve extension 410, is illustrated in Figure 36 with the shoulder 401 and the shoulder 430 in contact. This also represents the closest approach of the anvil-carrying part 346 to the staple-carrying part 344 of the disposable cartridge. This position of closest approach is illustrated in Figure 7 and is selected to define a space between the two parts of the disposable cartridge that is equal to the mini-

mum spacing required to accommodate tissue from whatever hollow body organs are to be stapled by the instrument of the present invention.

With reference to Figures 9 through 27, the staple-carrying part 344 is an assembly comprised of a hollow main body portion or shell 440 having a cylindrical portion and a frusto-conical portion which terminates in a small diameter neck 441. As best seen in Figure 18, a staple guide member 448 provided with a projection 452 coacting with a slot 450 defined on the main body part 440 for rotational orientation is secured to the main body part 440. The guide member 448 forms a guide face 456 which defines two concentric circular series of spaced staple-receiving slots 458, see Figure 22. Holes 451 provide venting for the staple-carrying part 344. Received within the main body part 440, as shown in Figures 18 and 23, is a staple pusher assembly 460, which fits concentrically within the main body part 440. The rear portion of the staple ejection assembly 460 is defined by a pusher back 453 having a generally frusto-conical shape and containing vent holes 463. The forward portion of the staple pusher 460 is defined by a member 455 which contains two concentric rings of peripherally spaced fingers 462, each one of which is received within a staple receiving slot 458. The member 455 is secured to the pusher 453 by a suitable adhesive at a point 457. The rear end 461 of the staple pusher 453 is adapted to be contacted by the end of driver tube 350. Hence, upon advancing the staple pusher assembly 460 by driver tube 350, the fingers 462 will pass further into the staple receiving slots 458, pushing staples contained therein axially outwardly. The staple pusher 460 is reinforced with a plurality of ribs 464 (Figure 25), at least two of which are provided with suitable plastic projections or bosses 466. With reference to Figures 22 and 31 through 33, a knife 468 in the form of an open cup with the rim defining the knife edge 470 is mounted within the staple ejector assembly 460 by means of holes 473 through which the bosses 466 project. In mounting, the bosses 466 are "hot staked" to fasten the knife 468 onto a support ring 467 of the staple ejector assembly 460 so that advancement of the staple ejector 460 also advances knife 468. The knife 468 has vent holes 461 which communicate with the vent holes 463 in the pusher 453.

As best seen in Figures 16 through 19, a shell support liner 576 of generally cylindrical shape is press fitted into the end of the small diameter neck 441. The liner 576 contains a pair of bayonet projections 578 and a guide projection 580, all of which mate with slots 581-583, respectively, to ensure proper indexing of the liner 576 when it is fitted into the neck 441. Defined within the liner 576 is a tube bore 584 of predetermined depth and which is of sufficient diameter to be slidably mounted on the flanged end of tube 330. Contained within the liner 576 is a keyway 586, which mates with key 588 to ensure proper orientation of the staple-carrying part 344 with respect to the tube 330. An additional bore 710 of smaller diameter than bore 584 is provided for in liner 576; bore 710 is of sufficient diameter to allow tube 350 to freely slide there-

through. Bore 710, as viewed in Figure 17, contains a pair of inwardly extending support members 686, which pass through slots 353 (Figures 10 and 20) in pusher rod 350. The inner ends of members 686
 5 define both a diameter 689 which fits closely with rod 352, and two keys 687 and 688 which mate respectively with slots 458 and 459 in rod 352. The keys, 687 and 688, and the slots 458 and 459, are of two different widths so that there is only one
 10 position in a 360° rotation in which the parts can be assembled.

It is paramount that the anvil 530 be in precise alignment with cartridge part 344 in all respects. In the above construction, the cartridge is aligned and
 15 keyed to center rod 352. As will be explained below, the anvil 530 is also aligned and keyed to the same slots 458 and 459 in rod 352. Since rod 352 is the single member connecting cartridge 344 and anvil 530 during the stapling procedure, an alignment
 20 path through the least number of parts (in order to obtain a minimum build up of error through accumulated tolerances, clearances, etc.) has been provided.

When the staple-carrying part 344 of the disposable cartridge 340 is assembled onto the end of the
 25 outer tube 330 by means of bayonet-connecting sleeve 342 and the bayonet pins 578 of the main body part 440 as shown in Figures 10 through 15, the main body part 440 will be drawn to a position such
 30 that the staple ejector 460 will engage the free end of the driver tube 350 and then be moved slightly outwardly relative to the main body part 440. The staple-carrying part 344 will then be ready for use.

The anvil-carrying part 346 is illustrated in Figures
 35 9 and 34 through 41, inclusive, and comprises a body portion 510 of cup shape with a central hub 512 defining a knob-receiving bore 514 and "D" shaped bore 566. A knob 516 is received within the bore 514. A skirt 568, defined by the hub 512, projects over the
 40 bore 514 and engages the shoulder defined by the reduced section 522 to hold knob 516 captive in bore 514, but allowing it to rotate freely. A longitudinal bore 570 is provided in the knob 516. The bore 570, at its forward portion, contains internal threading
 45 520, which matches the threading at the end of rod 352. The bore 566 contains an inner flat portion 565 to accommodate the flat 500 at the end of rod 352. Holes 349 provide venting for the anvil carrying part 346. Metal anvil 530, having two concentric circular
 50 arrays of spaced staple-clinching grooves 532 and a central hole 533, is mounted onto body portion 510 by press-fitting. The central hole 533 has the same cross-sectional configuration as the "D" shaped bore 566. Outwardly projecting keys 541, 542 mate
 55 with slots 458, 459, respectively, on rod 352 to further ensure proper orientation of the anvil-carrying part 346 with the rod 352. The keys 541, 542 are of different widths so that there is only one position in a 360° rotation which will permit
 60 assembly. Thus the anvil 530 is keyed to rod 352 and slots 458, 459 therein in the same manner as is staple-carrying part 344. To emphasize, this construction provides a minimum build up in tolerances and clearances in the assembly path connecting the
 65 anvil and the staple-carrying part when the staples

are formed.

Anvil 530 supports a cutting block 544 of annular configuration, that cooperates with knife 468. Cutting block 544 is rubber, soft plastic, or the like. Anvil
 70 530 has vent holes 347 which communicate with vent holes 349 in body 510.

In operation, wing nut 360 is rotated to advance rod 352 out from the end of tube 330. A staple-carrying part 344 of a disposable cartridge 340 is
 75 fitted over rod 352 and tube 330 and attached to tube 330 by a bayonet mount which includes bayonet pins 578 in the cartridge 340 and bayonet-receiving slots 357 in the sleeve 342. As shown in Figures 10 through 15, bayonet-connecting sleeve 342 is slidably mounted on tube 330. A cutout portion 341 of
 80 sleeve 342 and a pin 343 in tube 330 ensure the proper orientation of the sleeve 342 when it is slidably mounted on tube 330. A retaining ring 345, mounted in a groove on the tube 330 and a wall 747
 85 in the sleeve 342, limit the return movement of the sleeve 342. A wall 349, defined by the flanged portion 351 of the tube 330 and a wall 353, defined by sleeve 342 in cooperation with spring 756 bias sleeve 342 rearwardly to hold cartridge 340 firmly
 90 against end of tube 351.

Next, the anvil-carrying part 346 is assembled onto the end of projecting rod 352. To this end, the knob 516 is grasped and the threaded end of rod 352 is introduced into the hole 570 having threaded portion
 95 520. Flat 500 of rod 352 is received at this time in "D" hole 565 of anvil 510 before the threading engages, whereafter, knob 516 is rotated to seat threaded end of rod 352 into the threaded portion 520 of hole 570 and draw the flat 500 into the "D" hole 565. Keys 541,
 100 542 assure that staple-carrying slots 458 and staple-clinching grooves 532 are optimally aligned. As previously explained, keys 541, 542 are differently sized so that anvil 530 cannot be positioned 180° out of rotational alignment. Wing nut 360 is then rotated
 105 to retract rod 352 and thus bring anvil-carrying part 346 close to staple-carrying part 344.

In this condition, the instrument is inserted into the patient through the hollow organ that is to be stapled. At this time, the patient has been prepared
 110 such that the hollow organ to be stapled has been cut and there are two cut ends to be joined together by means of the instrument of the present invention. The instrument is inserted through the hollow organ until it projects from one of the cut ends. The wing
 115 nut 360 is rotated to extend the rod 352, thereby creating a substantial gap between the anvil carrying part 346 and the staple carrying part 344.

Now, the cut end of the hollow organ, through which the instrument is protruding, fashioned with a drawstring suture and drawn over the staple-carrying part 344 about the rod 352. The other cut
 120 end of the hollow organ is pulled over the anvil-carrying part 346 and, by means of a drawstring suture, is tied closely about the rod 352. Thus, the two cut ends of the hollow organ will be interposed between the anvil part 346 and the staple-carrying part 344. At this time, the wing nut 360 is rotated to cause retraction of the rod 352, whereupon the
 125 anvil-carrying part 346 will be brought into close proximity with the staple-carrying part 344. Wing nut
 130

360 is turned until marker ring 403 on rod 352 lies within the width of marker 404 on body 310. These marks have been pre-established to ensure that the tissue is clamped to a thickness which can be satisfactorily joined by the staples being used. The maximum clamping of tissue interposed between the staple-carrying part 344 and the anvil-carrying part 346 exists when shoulder 401 of rod 352 abuts shoulder 430 of bushing 704.

At this time, the rod 352 will occupy a position within the body 310 of the instrument, either as shown in solid lines in Figure 7 with the stop 401 bearing against the stop 430, or due to a greater than minimum thickness of entrapped tissue, the stop 401 will be axially displaced off of the stop 430 to the left, as shown in phantom.

With the apparatus in the condition described, that is, with the cut ends of the hollow organ to be stapled drawn around the two disposable parts of the cartridge, the safety 318 is released by pivoting away from the handle part 314 toward the handle part 312 in the manner shown in Figure 3, and the handle is grasped with the handle part 312 resting in the palm of the hand and the fingers curled about the handle part 314. When the fingers are drawn toward the palm of the hand in the manner of making a fist, the handle part 314 will be rotated about its pivot pin 316 clockwise, as shown in Figure 7, toward the handle part 312. This causes the yoke 390 to advance the pusher hub 372 axially to the left, as shown in Figure 7, and as indicated by the arrow. This action will force the driver tube 350, which is mounted into the hub 372 to the left as viewed in Figure 7, against the bias of spring 356. Advancement of driver tube 350 will, in turn, produce an advancement of the staple pusher 460, since the rear end 461 of this part is in contact with the end of the driver tube 350.

Advancement of the staple pusher 460 will cause the fingers 462 to move through the respective slots 456 ejecting the staples 159 contained therein. The action of the fingers 462 against the staples 159 is depicted in Figures 18 and 36; the forward faces of the fingers 462 are all provided with a V-groove 463 in which the crossbar of the U-shaped staple 159 is received. This assures a better contact between the finger 462 and the staple 159 during ejection.

Referring to Figures 16, 18, and 36 through 39, the action that takes place during ejection of the staple 159 is generally depicted; as the staples 159 are advanced or ejected out from the slots 458, they are contacted by grooves 532 of the anvil 530 and bent into a conventional B-shape, as depicted in Figure 38. Simultaneously with the advancement of the staple pusher 460, the knife 468, which is carried by the staple pusher 460, is axially advanced toward the anvil-carrying part and the knife edge 470 of the knife 468 will intersect with the interposed tissue ends of the trapped hollow organs. The cutting edge 470 of the knife 468, which is circular in configuration, cuts through the tissues of the hollow organs and into the annular cutting block 544, which is held within the anvil as previously described. The driver tube 350 will travel whatever distance is necessary to bend the staples always into the same configuration.

There is, of course, a maximum limit to tissue

thickness which a specific staple length can accommodate as shown by marks 404 and 403.

The excess portion of the ends of the hollow organ to be joined are severed by the action of knife edge 470. The vent holes 347 in anvil 530, and vent holes 449 formed in the body 510, as well as vent holes 451, 461 and 463 in the staple-carrying portion 344, allow for relief of gas, fluid or excess tissue trapped within the instrument on account of the procedure of stapling. The severed ends of the hollow organ are retained around rod 352 and between the anvil-carrying part and the staple-carrying part.

The next step in the procedure would be to rotate wing nut 360 to increase the spacing between the anvil-carrying part and the staple-carrying part to allow the stapled part of the hollow organ to be withdrawn from between these instrument parts and passed over the anvil-carrying part 346, so that the instrument may be withdrawn. To this end, the anvil carrying part 346 is provided with an external configuration typically of spherical dish-shape to facilitate the removal of the stapled organ from between the two parts 346 and 344 and passing of the stapled part of the organ over part 346. The removal is best accomplished when the perimeter of the profile, in section through the axis as shown in Figure 34, of the anvil-carrying part 346 is equal to or less than the circumference of the inner ring of staples represented by the inner circular array of spaced staple clinching grooves 532 in Figure 35.

Although the present invention has been shown and described in terms of a preferred embodiment, it will be appreciated that various changes may be made without departing from the spirit of the concept.

CLAIMS

1. A surgical stapling apparatus, at least part of which fits within two disconnected sections of hollow body organs, for the purpose of joining said sections with an arrangement of staples which forms a closed pattern, said apparatus comprising:
 - a rod;
 - a rigid first part including a staple guide body defining a closed pattern of staple holding grooves, within which said staples are carried, said first part being directly mounted on and keyed to said rod; and
 - a rigid anvil-carrying part including a closed pattern of spaced staple-clinching grooves against which said staples are formed, said anvil-carrying part being directly mounted on and keyed to said rod.
2. The surgical stapling apparatus of claim 1, wherein said rigid anvil-carrying part is fixedly mounted on said rod.
3. The surgical stapling apparatus of claim 1, wherein said rigid first part is slidably mounted on said rod.
4. A surgical stapling apparatus, at least part of which fits within two disconnected sections of hollow body organs, for joining said sections with an arrangement of staples which forms a closed pattern, said apparatus comprising:

- a rod;
a rigid first part including a staple guide body defining a closed pattern of staple holding grooves within which said staples are carried;
- 5 a rigid anvil-carrying part including a closed pattern of spaced staple clinching grooves against which said staples are formed;
first means directly mounting said rigid first part on said rod in a predetermined indexed orientation;
- 10 and
second means directly mounting said rigid anvil-carrying part on said rod in a predetermined indexed orientation.
5. The stapling apparatus of claim 4, wherein
15 said first means comprises at least one keyway on said rod and at least one key on said rigid first part.
6. The stapling apparatus of claim 4, wherein
said second means comprises at least one keyway on said rod and at least one key on said rigid
20 anvil-carrying part.
7. A surgical stapling apparatus for anastomosing two disconnected sections of hollow organs, said stapling apparatus comprising:
a body defining a bore;
- 25 a tubular member received within said bore arranged for reciprocation motion;
first means to reciprocate said tubular member;
a rod mounted to reciprocate concentrically within said tubular member;
- 30 second means to reciprocate said rod;
a two-part disposable cartridge assembly comprised of a rigid staple-carrying part and a rigid anvil-carrying part;
first means directly mounting said anvil-carrying
35 part on said rod in a predetermined indexed orientation; and
second means directly mounting said staple-carrying part on said rod in a predetermined indexed orientation.
- 40 8. The stapling apparatus of claim 7, wherein said first means comprises at least one keyway on said rod and at least one key on said rigid first part.
9. The stapling apparatus of claim 7, wherein
said second means comprises at least one keyway
45 on said rod and at least one key on said rigid anvil-carrying part.
10. A surgical stapling apparatus for anastomosing two disconnected sections of hollow organs, said stapling apparatus comprising:
a body defining a bore;
- 50 a tubular member received within said bore arranged for reciprocation motion;
first means to reciprocate said tubular member;
a rod mounted to reciprocate concentrically within
55 said tubular member, said rod including at least one keyway;
second means of reciprocate said rod;
a two-part disposable cartridge assembly comprised of a rigid staple-carrying part and a rigid anvil-
60 carrying part;
said staple-carrying part including first means operatively associated with said at least one keyway for directly mounting said staple-carrying part in a predetermined indexed orientation on said rod; and
65 said anvil-carrying part including second means

operatively associated with said at least one keyway for directly mounting said anvil-carrying part in a predetermined indexed orientation on said rod.

11. The apparatus of claim 10, wherein said first
70 means comprises at least one key.

12. The apparatus of claim 10, wherein said second means comprises at least one key.

13. The stapling apparatus of claim 10, wherein
said rod includes first and second keyways of
75 different dimensions, said first means includes first and second keys configured to mate, respectively, with said first and second keyways, and said second means includes third and fourth keys configured to mate, respectively, with said first and second key-
80 ways.

14. A surgical stapling apparatus having a disposable cartridge comprising, as a unit or otherwise, a staple carrying member and an anvil member; the
apparatus having means for adjusting a gap be-
85 tween these two members such that tissue to be joined can properly be accommodated between them before firing the staples.

15. An apparatus according to claim 14, in which
the cartridge is attached to the remainder of the
90 apparatus by a bayonet fixing.

16. A disposable cartridge for use as part of an apparatus according to claim 14 or claim 15, comprising, as a unit or otherwise, an anvil member, and a staple carrying member pre-packed with staples.